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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,661	10/28/2003	Gerald Czygan	117163.00094	4060

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EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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08/24/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
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Office Action Summary

Application No.

10/695,661

Applicant(s)

CZYGAN, GERALD

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-17,28,30,32,34,35,38-40,42,43,45-47,49-52,54-57,59-62 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,8-17,28,30,32,34,35,38-40,42,43,45-47,49-52,54-57,59-62 and 64.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 13, 2007. Claims 1, 3-5, 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62 and 64 are pending.

Response to Arguments

2. Applicant's arguments, see page 13, lines 25-28 and page 14, lines 1-7, filed June 13, 2007, with respect to the rejection(s) of claim(s) 1, 3-5, 46 and 50-51 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of different interpretations of the previously applied reference to Prutchi et al. (U.S. 6,141,585) and reconsideration of the previously cited reference to Schroepel (U.S. 5,431,693).

Allowable Subject Matter

3. The indicated allowability of claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 is withdrawn in view of different interpretations of the previously applied reference to Prutchi et al. (U.S. 6,141,585), reconsideration of the previously cited reference to Schroepel (U.S. 5,431,693) and in view of newly cited reference(s) to Lewyn et al. (U.S. 4,114,627) and Sholder (U.S. 4,686,988).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. *Claims 1, 3-4, 8-11, 35, 46 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi et al. (U.S. 6,141,585) (herein Prutchi) in view of Schroepel (U.S. 5,431,693).* As to Claims 1, 8-11, 35 and 50-51, Prutchi discloses a cardiac stimulator, read as a device 400 for delivering electrical stimulation pulses to body tissue through unipolar and/or bipolar electrode configurations. The device 400 comprises atrial tip electrode 410, atrial ring electrode 420, ventricular tip electrode 440, ventricular ring electrode 450 and can electrode 401 (see Prutchi Abstract, Figs. 4-5, column 7, lines 15-32 and lines 65-67 and column 8, lines 1-45). Prutchi discloses that any of the probable unipolar or bipolar electrode configurations discussed with reference to Fig. 4 are synonymous with the stimulation electrode 520 discussed with reference to Fig. 5 (see Prutchi column 10, lines 6-14). The device 400 of Prutchi further comprises a reservoir tank capacitor, read as energy storage means C_T for providing electrical stimulation energy to the stimulation electrode 520 from a voltage source, read as an energy source V_i . The device 400 further comprises a charging switch, read as a first switch SW1 with which the energy storage means C_T is switchably connected to the energy source V_i for charging the energy storage means C_T (see Prutchi column 9, lines 20-53). The device 400 of Prutchi further comprises a lead, read as an electrode connection 505 for connecting the stimulation electrode 520 to the device for delivering electrical stimulation pulses to body tissue and a pacing switch, read as a second switch SW2 with which the energy storage means C_T is switchably connected to the electrode connection 505 for delivery of a stimulation pulse via electrode 520 (see Prutchi column 9, lines 53-62).

Prutchi further discloses a discharge switch, read as a short-circuit switch SW3 with which the electrode connection 505, after delivery of the stimulation pulse is switchably

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connected to a ground potential (see Prutchi Fig. 5) such that, in the case of a connected and implanted electrode 520 a capacitance can be discharged by way of the body tissue, where the capacitance includes at least one Helmholtz capacitance C_L produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or body tissue. The device 400 further comprises a processor, read as a control unit 470 which is connected to at least the first switch SW1, the second switch SW2 and the short-circuit switch SW3 for switching the respective switches and which is adapted to separate the electrode connection 505 from the energy storage means C_T after delivery of the stimulation pulse and at least indirectly connect the electrode connection 505 to the ground potential (see Prutchi Figs. 3A-3B, column 3, lines 5-67, columns 4-5, column 6, lines 1-52, column 9, lines 20-67 and columns 10-12). Prutchi discloses the claimed invention as previously discussed except that it is not specified that the device 400 further comprise a means for monitoring stimulation outcome that, at least after delivery of a stimulation pulse, is connected to the electrode connection 505 and is adapted to detect a drop in voltage over time at the capacitance or a rise in short-circuit current over time at the capacitance, either being representative of a characteristic drop in a myocardium impedance of the body tissue indicating stimulation success.

Schroeppel, however, discloses a method for automatically verifying capture of the heart following application of an electrical stimulation pulse by a pacemaker 10 in order to consistently assure therapeutic efficacy while maximizing the life of the pacemaker's 10 battery or power source as conventional and well known in the art (see Schroeppel column 1, lines 1-54 and column 2, lines 33-41). The method of Schroeppel is additionally advantageous because the same electrode(s) that is/are used to deliver the stimulating pulse can also be used for detecting

non-capture or capture and non-capture or capture can be detected within 70 ms after delivery of the pacing pulse, which is early enough to permit a backup pacing pulse to be delivered immediately, if desired (see Schroepel column 5, lines 12-29).

The improved pacemaker 10 of Schroepel comprises a capture sense signal processor 58 and a microprocessor 20, collectively read as a means for monitoring stimulation outcome, at least after delivery of a stimulation pulse. Capture sense signal processor 58 of the means for monitoring is connected to the same electrode connection that delivered the stimulation pulse and is adapted to subsequently detect a drop in voltage over time at the capacitance of the electrode connection, inherently representative of a characteristic drop in a myocardium impedance of the body tissue, indicating stimulation success (see Schroepel Figs. 1-5 and column 5, lines 1-11 and lines 29-61). The microprocessor 20 of the means for monitoring stimulation outcome differentiates the detected voltage of the stimulation outcome in order to provide enhanced non-capture/capture verification processing (see Schroepel column 2, lines 44-61 and column 6, lines 22-35). Schroepel further discloses that threshold value detectors within microprocessor 20 determine whether a detected drop in voltage (i.e. $A_2 - A_1$) is above or below a predetermined limit value Ref_1 and whether the derivative of the detected voltage, standardized by taking its absolute value, is above or below a threshold value Ref_2 . Capture is determined or verified when the detected drop in voltage (i.e. $A_2 - A_1$) is above predetermined limit value Ref_1 and when the derivative of the detected voltage, standardized by taking its absolute value, below a threshold value Ref_2 at the expiration of a capture detect window see Schroepel Fig. 9 column 6, lines 36-68 column 7 and column 8, lines 1-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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device 400 of Prutchi, such that it comprises a means for monitoring stimulation outcome that, at least after delivery of a stimulation pulse, is connected to the electrode connection 505 and is adapted to detect a drop in voltage over time at the capacitance, as taught by Schroepfel such that stimulation success is automatically and assuredly verified, using the same electrode connection 505 in order to consistently assure therapeutic efficacy while maximizing the life of the devices energy source V_i .

6. As to Claims 3-4, in addition to the arguments previously presented, Prutchi further discloses that the capacitance also comprises a DC blocking capacitor, read as a coupling capacitor C_B that is connected between the electrode connection and the ground potential when the short-circuit switch SW3 is closed. Prutchi further discloses that the coupling capacitor C_B is arranged between the energy storage means C_T and the electrode connection in such a way that the coupling capacitor C_B is connected in series with the energy storage means C_T when the second switch SW2 is closed (see Prutchi Fig. 5).

7. As to Claim 46, in addition to the arguments previously presented, Prutchi discloses that in the unipolar electrode configurations, the ground potential of the device 400 includes a housing of the device or a surface portion thereof (see Prutchi Fig. 3B and column 3, lines 5-65).

8. *Claims 5, 28, 30, 32, 34 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepfel as applied to claims 1 and 3-4 above, and further in view of Lewyn et al. (U.S. 4,114,627) (herein Lewyn).* The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the device include a means for monitoring stimulation output include a means for detecting the voltage at the coupling capacitor. Lewyn, however, teaches that it is well known in

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the art of implantable pacer systems to include a means for measuring a residual voltage remaining on discharge coupling capacitor C1 such that an input coupling capacitor C3 of the pacer system's sense amplifier 20 (i.e. a sense output amplifier that senses stimulation outcome after delivery of a stimulation pulse) may be charged to a voltage sufficient to offset the residual voltage of coupling capacitor C1 in order to avoid overloading of the amplifier 20 (see Lewyn Fig. 1, column 6, lines 21-68, column 7, lines 1-64, column 8, lines 12-30 and column 9, lines 9-68, column 10 and column 11, lines 1-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi in view of Schroepel, such that the means for monitoring stimulation outcome, including the sense amplifier 62 of capture sense signal processor 58 and a microprocessor 20, include a means for measuring residual voltage charge remaining on the coupling capacitor, as taught by Lewyn in order to avoid overloading the means for monitoring stimulation outcome after delivery of a stimulation pulse.

9. *Claims 12-15, 40, 43, 47 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepel as applied to claims 1, 3-4 and 8-11 above, and further in view of Sholder (U.S. 4,686,988).* The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the device include a timer, connected to the means for monitoring stimulation outcome, where the timer measures the time duration between delivery of the stimulation pulse and the occurrence of the stimulation outcome or that the control unit receives the measured duration in order to set or adjust the strength of the stimulation pulse. Sholder, however, teaches that it is well known in the art for pacemakers to comprise a counter, read as a timer 144, where the timer 144 measures

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the time duration between delivery of the stimulation pulse and the occurrence of the stimulation outcome such that pulse generator logic circuitry 154 receives the measured duration and sets or adjusts the strength of the stimulation pulse through in order to maintain capture (see Sholder Abstract, column 3, lines 13-68, column 10, lines 30-68 and column 11, lines 1-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Prutchi in view of Schroepel and Sholder, such that, in order to maintain capture, the means for monitoring stimulation outcome includes a timer for measuring time duration between delivery of the stimulation and the occurrence of the stimulation outcome and further such that that the control unit receives the measured duration in order to set or adjust the strength of the stimulation pulse.

10. *Claims 16-17, 57 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepel and Sholder as applied to claims 1, 3, 8-15, 40, 43, 47 and 52 above, and further in view of Paul (U.S. 5,713,931).* The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the energy source V_i include a charge pump. Paul, however, teaches that it is well known in the art for an implantable pacemaker 10 to include a charge-pump voltage multiplier 48 providing a means to multiply or otherwise step up a voltage provided by a typical battery 46 to a reservoir tank capacitor 54 for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse which corresponds to pacing amplitude defined by a microprocessor 14 of the pacemaker 10, irrespective of battery 46 depletion (see Paul column 2, lines 5-13, column 3, lines 7-15 and lines 62-67 and column 4, lines 1-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the device as taught by Prutchi in view of Schroepel and Sholder, to include a charge pump as taught by Paul, for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse irrespective of battery depletion.

11. *Claims 42, 45, 49 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepel and Lewyn as applied to claims 5, 28, 30, 32, 34, 39 above, and further in view of Sholder.* The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the device include a timer, connected to the means for monitoring stimulation outcome, where the timer measures the time duration between delivery of the stimulation pulse and the occurrence of the stimulation outcome or that the control unit receives the measured duration in order to set or adjust the strength of the stimulation pulse. Sholder, however, teaches that it is well known in the art for pacemakers to comprise a counter, read as a timer 144, where the timer 144 measures the time duration between delivery of the stimulation pulse and the occurrence of the stimulation outcome such that pulse generator logic circuitry 154 receives the measured duration and sets or adjusts the strength of the stimulation pulse through in order to maintain capture (see Sholder Abstract, column 3, lines 13-68, column 10, lines 30-68 and column 11, lines 1-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Prutchi in view of Schroepel, Lewyn and Sholder, such that, in order to maintain capture, the means for monitoring stimulation outcome includes a timer for measuring time duration between delivery of the stimulation and the occurrence of the stimulation outcome and further such that that the control unit receives the measured duration in order to set or adjust the strength of the stimulation pulse.

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12. *Claims 55-56 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepfel as applied to claim 1 above, and further in view of Paul.*

The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the energy source V_i include a charge pump. Paul, however, teaches that it is well known in the art for an implantable pacemaker 10 to include a charge-pump voltage multiplier 48 providing a means to multiply or otherwise step up a voltage provided by a typical battery 46 to a reservoir tank capacitor 54 for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse which corresponds to pacing amplitude defined by a microprocessor 14 of the pacemaker 10, irrespective of battery 46 depletion (see Paul column 2, lines 5-13, column 3, lines 7-15 and lines 62-67 and column 4, lines 1-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi in view of Schroepfel, to include a charge pump as taught by Paul, for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse irrespective of battery depletion.

13. *Claims 59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Schroepfel, Lewyn and Sholder as applied to claim 54 above, and further in view of Paul.* The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the energy source V_i include a charge pump. Paul, however, teaches that it is well known in the art for an implantable pacemaker 10 to include a charge-pump voltage multiplier 48 providing a means to multiply or otherwise step up a voltage provided by a typical battery 46 to a reservoir tank capacitor 54 for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse which

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corresponds to pacing amplitude defined by a microprocessor 14 of the pacemaker 10, irrespective of battery 46 depletion (see Paul column 2, lines 5-13, column 3, lines 7-15 and lines 62-67 and column 4, lines 1-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi in view of Schroepfel, Lewyn and Sholder, to include a charge pump as taught by Paul, for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse irrespective of battery depletion.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Hoegnelid et al. (U.S. 5,405,365) discloses a differential stimulation outcome means 43 for detecting a voltage drop across cardiac tissue following the delivery of a stimulation pulse.

Noren et al. (U.S. 2003/0009200) teaches that capture or non-capture may be verified by comparing measured impedance, or a characteristic thereof, to known thresholds for either capture or non-capture.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
August 16, 2007

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
August 17, 2007